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REMARKS

Reconsideration of the application as amended is requested.

A two-month extension of time is requested, and a separate petition and fee to this effect are enclosed. Claims 1-7, 25-34 and 41 have been amended and new claims 42-57 have been added.

In the Office Action dated October 11, 2005, claim 34 was rejected under 35 U.S.C. §112, first paragraph. The Office Action states that "More specifically, the introduction of 'including adhesive contacting overlapping portions' into claim 34 invokes new matter since the Applicant has not provided support in the original specification or claims for this limitation."

At page 3, lines 9-10, the present application states that "a suitable thickness for film 13 is about 1 mil." At lines 13-22, the present application states:

Handles 11 are preferably made of plastic or paper, or silicone coated paper, with the silicone coat on the upper surface thereof. Paper handles 11 are shown in Figs. 1 and 2. The entire undersurface of each of handles 11 is coated with a pressure sensitive adhesive, which is moderately aggressive with respect to polymeric film 13, but which does not adhere or adheres less aggressively to either the silicone coating 16 on release liner 15 or to human skin. In this way, a user can readily fold back the end portion of release liner 15 to expose the end of one of the handles 11, and the exposed handle 11 can then be used to peel film 13 away from release liner 15. The adhesive of layers 12 is "moderately aggressive" in that handles 11 remain attached to polymeric film 13 when it is peeled away from release liner 15, and while it is being handled and applied to the patient's skin.

Given that the handles 11 are made of paper, and the film is only 1 mil thick, one skilled in the art would readily understand that at least some of the pressure sensitive adhesive on the underside of handles 11 contact the release liner 15. Clearly, there would be no reason to discuss the adhesive properties of the PSA relative to the silicone coating 16 on release liner 15 if the adhesive did not contact coating 16 of liner 15.

Significantly, claim 34 was not rejected over the cited references. According to MPEP 2163.06(I),

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If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (CCPA 1981). The examiner should still consider the subject matter added to the claim and making rejections based on prior art since the new matter rejection may be overcome by applicant.

Applicant presumes the Examiner has examined claim 34 as required by the MPEP, and found claim 34 to be allowable over the prior art.

The Office Action also states that "The indicated allowability of claims 25-33 and the indication that claim 5 contains allowable subject matter is withdrawn in view of the *newly discovered references* [sic] to Session [sic] et al." (Emphasis added.) An Information Disclosure Statement ("IDS") listing Sessions et al. U.S. Patent No. 6,043,406 was filed on April 11, 2002, and the IDS (copy enclosed) was initialed by the Examiner and dated October 8, 2003 indicating that the citation was considered. Claim 25 is still in the identical form in which it was filed on February 7, 2002. It is unclear why Sessions '406 is only now being cited, well over three years since the Examiner first considered Sessions '406.

MPEP 706.04 states that "A claim noted as allowable shall thereafter be rejected only after the proposed rejection has been submitted to the primary Examiner for consideration of all the facts and approval of the proposed action. Great care should be exercised in authorizing such a rejection." See *Ex parte Grier*, 1923 C.D. 27, 309 O.G. 223 (Comm'r Pat. 1923); *Ex parte Hay*, 1909 C.D. 18, 139 O.G. 197 (Comm'r Pat. 1909) (Emphasis added.).

Further, 37 C.F.R. §104(c)(2) states "In rejecting claims for want of novelty or for obviousness, the Examiner must cite the best references at his or her command." (Emphasis added.) Still further, MPEP 706 states that "The goal of examination is to clearly articulate any rejection early in the prosecution process so that the Applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity." (Emphasis added.) Clearly, this goal is not being achieved in the present application.

In the Office Action dated October 11, 2005, claims 1-5 and 41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sessions '406. Claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sessions '406 in view of Heinecke et al. U.S.

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Patent No. 5,520,629. Claims 25-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sessions '406 in view of Ward U.S. Patent No. 4,753,232. Claims 30-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sessions '406 in view of Ward '232 and further in view of Heinecke '629. Applicant respectfully asserts that all of the pending claims patentably distinguish over the cited references for those reasons set forth in more detail below.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP 2143; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For those reasons set forth in more detail below, Applicant asserts that Sessions '406 does not establish a *prima facie* case of obviousness, such that a "critical teaching" and/or a showing of "unexpected results" is not required to establish patentability. More specifically, claim 1 recites a handle adhered to a second non-adhesive side of a polymeric film with a pressure sensitive adhesive, with a portion of the handle projecting beyond a first edge of the polymeric film and overlying a release liner. Contrary to the arrangement of claim 1, Sessions '406 teaches a tab 32 and intermediate liner 34 to separate the cover sheet from the release liner. Furthermore, as discussed in more detail below, the underside of cover sheet 16 of Sessions '406 never contacts the skin of a patient. Thus, there would be no reason to utilize a pressure sensitive adhesive in the Sessions '106 dressing.

Release tabs as taught by Sessions '406 are not required in the medical adhesive device of claim 1 because the pressure sensitive adhesive provides relatively little or no adhesion between the handle and the release liner. Use of separate tabs as taught by Sessions '406 adds substantially to the cost and complexity of the Sessions' dressing. Applicant submits that Sessions '406 would not teach such a complicated arrangement if, in fact, it would have been

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obvious to simply utilize a pressure sensitive adhesive. Furthermore, there is no suggestion or motivation in Sessions '406 to provide a pressure sensitive adhesive as required by MPEP 2143, discussed above.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP 2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Tab 32 of Sessions '406 prevents the lower side of cover sheet 16 from contacting a patient's skin, and this teaches away from the arrangement of claim 1. Applicant further notes that "It is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also *In re Mercer*, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975). Applicant asserts that a full appreciation of Sessions '406 does not suggest modification to utilize pressure sensitive adhesive.

Applicant further notes that it is not at all clear that Sessions '406 would function properly if pressure sensitive adhesive were utilized between cover sheet 16 and film 14. Specifically, it is not clear if cover sheet 16 could be pulled away from tab 32 in use as shown in Fig. 5. If the upper surface of tab 32 were coated with silicone, or tab 32 were made of a low-adhering material, it is not clear if tab 32 would remain adhered to adhesive 28 at releasable end 24 as shown in Fig. 5. Alternately, if the upper surface of tab 32 were made of a material that is readily adhered to, it is not clear if a user could peel the end of cover sheet 16 at second tab 36 off tab 32 as shown in Fig. 5. Furthermore, it is not at all clear that adhesive coated surface 28 would have sufficient adhesive properties relative to a patient's skin to prevent film 14 from lifting off a patient's skin as cover sheet 16 is pulled away (Fig. 5). Sessions '406 states that film 14 is preferably formed or cast directly on cover sheet 16, and adhesive is not necessary. Col. 4, lines 17-27. Sessions '406 does not fairly suggest to one of ordinary skill in the art that pressure sensitive adhesive be selected, and further that an

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adhesive having greater adhesion be selected for coating 28, particularly given that cover sheet 16 never contacts a patient's skin.

Still further, claim 1 states that "said first adhesive on said first side of said polymeric film adhering more aggressively to skin than said pressure sensitive adhesive adheres to said polymeric film." The underside of cover sheet 16 of Sessions '406 never comes into contact with a patient's skin. Specifically, with reference to Figs. 4-6, tab 32 prevents contact at the left end of dressing 10, and the right end of film 14 and tab 34 both prevent contact between cover sheet 16 and the patient's skin. Thus, Sessions '406 actually teaches that contact between cover sheet 16 and a patient's skin is to be avoided. Certainly this falls far short of a teaching or suggestion to provide a pressure sensitive adhesive having the adhesive properties recited in claim 1. Substantial modification of Sessions '406 would be required to provide the arrangement of claim 1, and the reference itself does not in any way teach or suggest such modification. According to MPEP 2443.02, a reasonable expectation of success is required to establish a *prima facie* obviousness. Applicant asserts that Sessions '406 does not provide a reasonable expectation of success given the substantial modifications that would be required.

Also, Sessions '406 states that:

Referring again to FIGS. 2-3, the adhesive side 23 of the left and right releasable ends 24, 26 are capable of receiving and carrying first tab 32 and an intermediate liner 34, respectively. The intermediate liner 34, disposed between the cover sheet 16 and the carrier sheet 18, covers substantially all of the right releasable end 26 so that the adhesive side 28 of the right releasable end 34 [sic] 26 does not adhere to the carrier sheet 18. The first tab 32, which extends outboard of the left end of the cover sheet 16, is similarly disposed between the cover sheet 16 and the carrier sheet and covers substantially all of the left releasable end 24 so that the adhesive side 28 of the left end 24 does not adhere to the carrier sheet 18. The faces of the first tab 32 and the intermediate liner 34 in adjacent contact with the carrier sheet 18 do not carry an adhesive so that they do not adhere to the release side 20 of the carrier sheet 18.

(Col. 5, lines 26-41). Thus, Sessions '406 actually teaches use of a non-adhesive surface formed by a separate piece to prevent adhering to carrier sheet 18. The Office Action states that:

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Sessions et al. fail to teach that the adhesive on cover sheet (sheet), which forms a handle, is a pressure sensitive adhesive. Absent a critical teaching and/or a showing of unexpected results derived from using a pressure sensitive adhesive on the handle, the examiner contends that any adhesive can be used to secure the handle to the polymeric film.

Moreover, Sessions et al. is silent as to the criticality of the type of adhesive used to secure the cover sheet, which forms the handle, to the film. Thus, it would have been an obvious design choice to one having ordinary skill in the art to use a pressure sensitive adhesive or any other type of adhesive to secure the cover sheet of Sessions et al. to the film. Additionally it appears that the device of Sessions et al. would perform equally well with a pressure sensitive adhesive used to secure the cover sheet to the film layer.

The statement that "any adhesive can be used to secure the handle to the polymeric film" is clearly a factually incorrect statement. For example, if an adhesive having very high adhesive properties were utilized, the cover sheet 16 of Sessions '406 could not be peeled away from film 14 during application of the dressing 10 as illustrated in Fig. 5. If the Examiner is relying on knowledge generally available to one of ordinary skill in the art, Applicant respectfully requests that the Examiner articulate that knowledge and place it on the record. *See In re Lee*, 277 F.3d 1338, 1345, 61 USPQ2d 1430, 1433-35 (Fed. Cir. 2002) (when an Examiner relies on general knowledge to negate patentability, that knowledge must be articulated and placed on the record). *See also In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Furthermore, MPEP 2143.01(III) states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Thus, even if the statement that "any adhesive *can be* used to secure the handle to the polymeric film" were true, it would not establish a *prima facie* obviousness.

Also, with respect to the statement that "Sessions et al. is silent as to the criticality of the type of adhesive used", and "absent a critical teaching and/or a showing of unexpected results", Applicant respectfully points out that a "critical teaching" or "showing of unexpected

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results" are not one of the three basic criteria that must be met to establish a *prima facie* case of obviousness. See MPEP 2143; *In re Vaeck, supra*. The statements concerning the failure of Sessions with respect to a "critical teaching" or "unexpected results" is tantamount to a fourth requirement for establishing a *prima facie* case of obviousness, namely that the prior art teach that its disclosure is critical and/or that Applicant show "unexpected results". MPEP 2141(I) states that "Patent examiners carry the responsibility of making sure that the standard of patentability annunciated by the Supreme Court and by the Congress is applied in each and every case."

As discussed in detail above, a *prima facie* case of obviousness has not been established. Nevertheless, Applicant asserts that the use of pressure sensitive adhesive actually does provide an unexpected result. Specifically, Sessions '406 teaches a first tab 36 that prevents contact between the lower surface of cover sheet 16 and a patient's skin (Fig. 5). The pressure sensitive adhesive of the present invention permits the handle to be adhered to the film, yet it does not require use of a tab, liner, or the like to prevent contact between the pressure sensitive adhesive and a patient's skin. Also, the pressure sensitive adhesive adheres less aggressively to the polymer film than the first adhesive on the film adheres to skin, thereby permitting the handle to be peeled off the film without peeling the film from a patient's skin. This is actually quite unexpected in view of Sessions '406.

Claims 2-3 and 6 depend from claim 1, and are therefore believed to be allowable for those reasons set forth above in connection with claim 1.

With respect to claim 5, Applicant asserts that claim 5 is allowable for substantially the same reasons as set forth above in connection with claim 1. Also, the Office Action states that "As can be seen from Figs. 2, 3 and 5, the psa neither adheres to the carrier sheet (18) nor to the skin." However, as discussed above, the underside of cover sheet 16 of Sessions '406 never contacts a patient's skin, and there would therefore be no reason to select a pressure sensitive adhesive for use in the Sessions '406 arrangement.

Applicant further asserts that Sessions '406 does not teach that the entire undersurface of cover sheet 16 is coated with an adhesive, and is quite unclear if Sessions '406 would be operable if this were the case. More specifically, with reference to Fig. 2 of Sessions '406, if

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the entire underside of cover sheet 16 were coated with adhesive, it would likely adhesively bond to first tab 32, making it very difficult to lift the edge of cover sheet 16 away from tab 32 as illustrated in Fig. 5 of Sessions '406. Furthermore, if the upper surface of first tab 32 were coated with a silicon release material, tab 32 would likely not adhere to adhesive 28 at releasable end 24 of film 14, contrary to the teachings of Sessions '406 which states that "the adhesive side 23 of the left and right releasable ends 24, 26 are capable of receiving and carrying first tab 32". Column 5, lines 26-28.

Still further, at column 5, lines 37-41, Sessions '406 states that "The faces of the first tab 32 and the intermediate liner 34 in adjacent contact with the carrier sheet 18 do not carry an adhesive so that they do not adhere to the release side 20 of the carrier sheet 18." Thus, Sessions '406 actually teaches that a surface having no adhesive is used to provide a non-adhering arrangement with respect to carrier sheet 18. Applicant reiterates that it is improper to pick and choose parts of a reference to the exclusion of other parts. *In re Wesslau, supra*.

Claims 5 and 7 depend from claim 4, and are therefore believed to be allowable for those reasons set forth above in connection with claim 4.

With respect to independent claim 25, Applicant asserts that claim 25 is allowable for substantially the same reasons as set forth above in connection with claims 1 and 4. Even if the underside of the cover sheet 16 of Sessions '406 were coated with pressure sensitive adhesive, the pressure sensitive adhesive would not contact a patient's skin because Sessions specifically teaches a tab 32 that would prevent any such contact. Accordingly, Sessions '406 does not even recognize the problems associated with an arrangement wherein the underside of a handle contacts a patient's skin. Rather, Sessions '406 teaches a tab that prevents any such contact.

Claims 26-33 depend from claim 25, and are therefore believed to be allowable for those reasons set forth above in connection with claim 25.

With respect to independent claim 41, Applicant asserts that claim 41 is allowable for substantially the same reasons as set forth above in connection with independent claims 1, 4 and 25.


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Applicant has added new claims 42-57. Each of the new claims is believed to patentably distinguish over the cited references.

Applicant has made a concerted effort to the place the present application in condition for allowance, and a notice to this effect is earnestly solicited. In the event there are any remaining informalities, the courtesy of a telephone call to the undersigned attorney would be appreciated.

Respectfully submitted,

3/13/06
Date


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